United States Department of Agriculture
Farm Service Agency
Commodity Operations

Total Quality Systems Audit

Supplier Guidelines

Form #: TQ-005
Revision 003
Date: 6/01/04

**(All previous forms and revisions are obsolete.
Please dispose and replace with this form.)**

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Section 1

General Guidelines

1. General Information

A. Overview

(1) The Total Quality Systems Audit (TQSA) is a fee-for-service program open to the food industry. Participation in TQSA may be required as a condition of doing business with United States Department of Agriculture/Commodity Credit Corporation (USDA/CCC). This requirement will be specified in the commodity purchase announcement/invitation or contract.

(2) TQSA does not excuse failure to comply with USDA/CCC contract requirements; Federal Food, Drug and Cosmetic Act (21 CFR); the Federal Acquisition Regulations (FAR); or other Federal, State, or local laws or regulations.

(3) Primary oversight and execution of TQSA is the responsibility of USDA, Farm Service Agency (FSA), Deputy Administrator of Commodity Operations (DACO). DACO divisions include the Kansas City Commodity Office (KCCO), and the Washington, DC offices of the Procurement and Donations and Warehouse and Inventory Divisions, FSA.

(4) TQSA is conducted in accordance with the Federal Acquisition Regulation (FAR) Part 9.1 (Contractor Qualifications) which outlines the policies, standards, and procedures for determining whether prospective contractors and subcontractors are responsible.

B. Confidentiality

All manuals and other data submitted under TQSA relevant to proposed or existing participation in the TQSA will be treated as proprietary information and will be held in the strictest confidence. Information gathered and/or reported by the auditors will also be treated as proprietary information and will be held in strictest confidence.

C. Applicability

(1) TQSA applies to all suppliers offering commodity for sale to USDA/CCC when TQSA is required by the purchase announcement/invitation or contract.

(2) Subcontractors utilized by a manufacturer or regular dealer to provide contracted end products(s) are subject to TQSA.

D. Scope

(1) These guidelines are meant to assist a supplier (or auditee) in complying with TQSA. All attempts have been made to ensure the completeness and accuracy of these guidelines; however, they are subject to change.

(2) What these guidelines cover

(a) Initiation of services
(b) Types of services offered
(c) Requirements
(d) Definitions

(3) What these guidelines do NOT cover
   (a) Contract terms (refer to the purchase announcement/invitation)
   (b) Bidder status with KCCO
   (c) Bidder eligibility

E. Fees are to the account of the supplier and must be paid in full for all services rendered. A fee schedule can be found in Section 2 of these guidelines.

F. Inquiries and More Information
   (1) Website: http://www.fsa.usda.gov/daco/pdd/tqsa.htm
   (2) General inquiries about TQSA should be directed to:
   Procurement and Donations Division
   USDA/FSA/PDD/Stop 0551
   1400 Independence Ave, SW
   Washington, DC 20250-0551
   PH: (202)720-5074
   FAX: (202)690-1809
   (3) Inquiries about fees and services should be directed to:
   Warehouse Licensing and Examination Division, Stop 9148
   Kansas City Commodity Office
   6501 Beacon Drive
   Kansas City, Missouri 64133-6476
   Ph: 816-926-6417
   Fax: 816-926-1774
   (4) Inquiries about procurement or contracting should be directed to:
   (a) Bulk Commodities Division, Stop 8748
   Kansas City Commodity Office
   6501 Beacon Drive
   Kansas City, Missouri 64133-6476
   Ph: (816)926-6420
   Fax: (816)823-1804
   (b) Dairy and Domestic Operations Division, Stop 8718
   Kansas City Commodity Office
   6501 Beacon Drive
   Kansas City, Missouri 64133-6476
   Ph: (816)926-6124
   Fax: (816)823-4195

(c) Export Operations Division, Stop 8738
Kansas City Commodity Office
6501 Beacon Drive
Kansas City, Missouri 64133-6476
Ph: (816)926-6707
Fax: (816)823-1640

2. General Requirements

A. Compliance

(1) To fulfill the obligation of contracts that require TQSA, or where the supplier voluntarily agrees to participate in TQSA, suppliers must:

(a) comply with these guidelines, and any applicable supplemental documentation;

(b) respond in a timely manner to all Corrective Action Requests issued during a TQSA; and

(c) be current on payment for all services rendered.

(2) KCCO will be notified of any suppliers not in compliance with TQSA for review and appropriate action.

B. A TQSA is conducted on an individual plant basis. Each production facility will be rated independently of its parent company, affiliations, and/or subsidiaries.

C. Product samples may be taken during the course of any TQSA. Suppliers may be required to provide assistance in the collection of samples. Samples will be submitted to the appropriate testing facility for analysis and review to verify compliance with applicable standards. If samples are drawn, suppliers will be notified of the amount of product sampled, where it was sent, what analyses were performed, the results of those analyses, and related costs.

3. Types of Service

A. Baseline

A baseline TQSA is a full audit done for a new or potential TQSA participant.

Scope:	Entire quality system
Location:	Supplier's facilities
	Primary manufacturers must be in operation
Participants:	TQSA Team
	Supplier management, quality assurance/control personnel, plant employees directly involved in production or quality assurance

B. Full TQSA

A full TQSA is a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Scope:	Entire quality system
Location:	Supplier's facilities
	Primary manufacturers must be in operation
Participants:	TQSA Team
	Supplier management, quality assurance/control personnel, plant employees directly involved in production or quality assurance

C. Surveillance

A surveillance TQSA is to confirm corrective actions have been completed and are successful, and to ensure continued conformance to the supplier?s stated quality management system.

Scope:	Partial (will be identified at opening meeting)
Location:	Supplier's facilities or via other communication as needed
Participants:	TQSA Team or individual auditor
	Supplier management, quality assurance/control personnel, or person responsible for completing corrective action requests

D. Destination Reviews

Destination reviews are conducted at a point in the commodity distribution chain for the purpose of verifying product conformance to the applicable standards.

Scope:	Product review and analysis
Location:	Any point during distribution to end-user
Participants:	TQSA Team or individual auditor
	Personnel presently responsible for product protection and distribution

4. Structure and Reporting

A. Pre-Audit

(1) Supplier must make the following information available when an audit is scheduled:

(a) Contact person name and title

(b) Contact person phone number, fax number and E-mail address (if available)

(c) Person with signatory authority for TQSA records (if different from contact person)

(d) USDA/CCC products being produced and production schedule if awarded a recent contract

(e) Hours of operation

(f) Location and directions to facility

(g) Company safety policies, where applicable

(2) TQSA scheduler will:

(a) Schedule audit and coordinate with supplier

(b) Notify TQSA team members

(3) Auditor will:

(a) Contact company representative for audit confirmation during the week prior to an announced scheduled TQSA (surveillance and destination reviews may be unannounced)

(b) Provide and obtain any supplemental information needed

B. Audit

(1) Supplier must make pertinent quality system paperwork available, including, but not limited to:

(a) Quality Policy

(b) Quality Manual(s)

(c) Organizational chart

(d) Production/Process flow chart(s) for USDA product

(e) Procedures and work instructions not contained in the quality manual

(f) Quality Records

(g) Production Records

(h) Shipping Records

(i) In-Process and final testing procedures and results

(j) Sub-supplier certifications/records

(k) Proof of U.S. origin requirements

(l) All USDA contract documents (including current contracts under or pending production)

(m) All documentation and records relating to the organization? s quality system not included in this list

(2) Supplier shall also make the following resources available:
   (a) Access to supplier's receiving, production (including laboratory) and distribution sites
   (b) Interview time with key personnel (will be identified from organizational chart)
   (c) Opportunity to talk with production level employees on site
   (d) Private working space for the TQSA team
   (e) Phone, copier, and fax machine access
   (f) Use of certified test equipment (e.g., weight scales)
   (g) Any required safety equipment (e.g., hardhats, bumpcaps, earplugs, or hairnets, as needed)
   (h) Personnel to accompany the auditors throughout their TQSA activities to provide guidance and assistance

(3) TQSA team will:
   (a) Present audit plan and schedule
   (b) Clarify audit procedures, guidelines, and requirements as needed
   (c) Conduct audit in professional manner
   (d) Where possible, ensure minimal disruption of supplier work environment
   (e) Communicate all findings to company representatives
   (f) Furnish a copy of completed TQSA report and corrective action requests (CARs)

(4) TQSA will consist of the following activities (not necessarily in this order):
   (a) Opening meeting
   (b) Plant walk-through (includes detailed facilities and equipment assessment, and review of production activities)
   (c) Interviews and observation of plant employees
   (d) Review of documentation and procedures
   (e) Review of records
   (f) TQSA team consultations
   (g) Preparation of TQSA report and corrective action requests
   (h) Closing meeting

(5) TQSA may also consist of product sampling as needed.

C. Post-Audit

TQSA team or auditors will:

(1) Furnish copy of TQSA Report, Summary, and CARs to KCCO, and TQSA management

(2) Ensure all corrective actions are followed-up and completed

5. Compliance

A. To be considered compliant with TQSA, suppliers must successfully conform to the following:
   (1) Current applicable commodity announcement/invitation requirements
   (2) Current Good Manufacturing Practices (GMPs) as amended (21 CFR Part 110)
   (3) Applicable Federal, State, and local food safety requirements
   (4) TQSA Report, Form TQ-003 contained in Section 4 of this guideline

B. Full compliance includes, but is not limited to: *documentation* of operating procedures, *consistent performance* of documented procedures, completion and retention of all applicable *records* (purchasing, analytical, processing, etc.), and adherence to contractual requirements.

C. All non-compliance observations and findings will be recorded by the TQSA team on Form TQ-003, TQSA Report. Evidence of major non-conformance or system failures will also be recorded on Form KC-03TQ, Corrective Action Request (CAR). The supplier will identify proposed corrective action plan on this form.

D. It is the responsibility of the suppliers to determine and make all necessary corrections in a timely manner. The suppliers will be given an opportunity after the TQSA to develop and implement a corrective action plan. The plan will state proposed course of action, or action taken, to remedy the problem and, where appropriate, expected time frame for completion. The plan or response must be submitted to the person indicated on the CAR within 10 working days. Auditors will follow-up to verify corrective action has been successfully made, and close the CAR.

E. The TQSA Report will be reviewed and scored prior to the closing meeting. Supplier will be able to review the report and dispute any findings at that time. Disputes may be settled by the presentation of additional information, or clarification of information. The report will be reviewed and necessary corrections made. All disputes will be settled at the closing meeting. The score presented at the end of the TQSA is final, and not subject to further review.

F. The TQSA Summary (Form KC-01TQ) and the CARs require the signature of the supplier's representative with the authority to sign or who has responsibility for plant operations. The contact person will be assumed to have this authority unless otherwise indicated by the supplier. Signature on the TQSA Summary constitutes agreement with the completed TQSA and all related records. Person with signatory authority must be present at the closing meeting.

G. TQSA Report, Summary, and CARs will be provided to KCCO. This information may be used in a determination of eligibility, awarding of contracts, or product acceptance or rejection.

6. Level Designations

A. Scores and Levels

(1) Scoring is done at the completion of baseline and full TQSAs. Scoring instructions can be found at the end of the TQSA Report, TQ-003 found in Section 4 of these guidelines.

(2) Scores will not be adjusted during surveillance visits, or destination reviews.

(3) Once a TQSA score has been calculated, a Frequency Level (FL) will be assigned. The FL does not impact bidder eligibility, but reflects the supplier's level of proficiency in the program.

(4) TQSA Scores and Corresponding FL

TQSA Score	**Frequency Levels (FL)**	**Number of full audits during a 12-month cycle**
90 - 100	I	1
80 – 89	II	2
Below 80	III	By suppliers request only

B. TQSA Frequency Levels

(1) Frequency Levels (FL) refer to a level of proficiency in the program, and determine the number of full TQSA during a 12 month cycle. This FL does not impact bidder eligibility, but is used to assess a supplier's ability to maintain the effectiveness of its quality management system. As a supplier's proficiency (as evidenced by score) increases, its FL (number of full audits during a 12 month cycle) decreases.

(2) All suppliers will be audited within 6 months of their baseline TQSA, regardless of TQSA score. This is to ensure the supplier has the ability to maintain the level assigned.

(3) **After baseline TQSA**, the following schedule applies:

TQSA Score	Frequency Levels (FL)	Number of full audits during a 12-month cycle
90 - 100	I	1
80 – 89	II	2
Below 80	III	By suppliers request only

(4) Suppliers are subject to 1-4 routine surveillance TQSA per year. Surveillance TQSA may be unannounced to the supplier.

(5) If a TQSA score is lower than the acceptable score for bidder eligibility, and the supplier has not previously been awarded a contract, the next full TQSA will be at the supplier's request. If the supplier has an outstanding contract to perform, appropriate FL for TQSA score will be applicable. Refer to purchase announcement/invitation or contract for more information.

(6) The FL does not preclude audits or reviews when deemed justified by KCCO and the TQSA review team. Reasons for additional audits or reviews include, but are not limited to, valid customer complaints, product non-conformances found during surveillance TQSA or destination reviews, or other contract non-conformances or non-fulfillment.

(7) Once a FL has been assigned, it can be changed according to the following parameters:

(a) FL Changes: When a supplier scores different than the last full TQSA, its FL will change to the corresponding FL immediately.

(b) No change: When a supplier scores within the same point bracket, its FL will not be changed.

7. Disclaimers

A. A TQSA is merely a "snap-shot" check of a supplier's quality management system, taken during a short, defined time period. It cannot find all defects in the supplier's system, but rather finds typical faults or trends. TQSA relies on sampling methods because the team members cannot check every detail during a TQSA. Non-discovery of a system failure does not absolve the supplier of its obligation and responsibility to comply with TQSA or any other contractual requirements and obligations.

B. TQSA does not excuse failure to comply with USDA/CCC contract requirements, Federal Food, Drug and Cosmetic Act (21 CFR), the Federal Acquisition Regulations (FAR), or other Federal, State, or local laws or regulations.

C. The ISO 9001:2000 Quality Standards are used as a reference model of a comprehensive quality management system.

8. Civil Rights

The United States Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (such as Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202)720-2600 (voice and TDD).

To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 1400 Independence Ave., SW, Washington, DC 20250-9410 or call (202)720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.

Section 2

Fee Schedule

1. TQSA Fee Schedule

Audit Type	Administrative Fee	Per Auditor Hourly Rate	Minimum Number of Auditors	Estimated Time per Auditor
Baseline	NC	NC	2	20 hours
Full	$500.00	$94.00	2	18 hours
Surveillance	NC	as applicable*	1	4 hours
Destination	NC	as applicable*	1	<4 hours

NC = No charge

*The supplier is subject to the per auditor hourly rate of $94 if audit is conducted as a result of supplier noncompliance.

2. On full, surveillance, and destination reviews, actual costs may be billed for the following:
   A. sampling
   B. commodity analyses
   C. grade analysis

3. Invoices will be generated by Warehouse Licensing and Examination Division (WLED), KCCO. Hours billed will be taken from the TQSA Summary Report, Form KC-01TQ when received in office. Those suppliers requesting monthly billing will be billed at the end of the month.

4. Invoices are due upon receipt. If payment in full is not made within 30 days from date of invoice, late payment interest at the annual rate specified in the Prompt Payment Act will be applied to the amount on a daily basis accruing from the invoice date until payment in full is received.

5. Payment to be made by check payable to Commodity Credit Corporation and mailed to:
   DMD-DCB, Stop 8528
   Kansas City Finance Office
   P.O. Box 419205
   Kansas City, MO 64141-6205

6. Past Due Balances:
   A. WLED will notify the supplier if the balance is 30 days past due.
   B. WLED will notify the contracting officer(s) if the balance is delinquent.
      WLED will request that DMD-DCB begin collection actions.
   C. If an account is delinquent, suppliers may be considered not in compliance with TQSA.

Section 3

Definitions

Audit (TQSA):	A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
Auditee:	An organization to be audited. In this guideline an auditee is considered to be one production facility, regardless of ownership status.
Auditor:	A person who has the qualifications and authorization to perform quality audits. A "lead auditor" is a person designated to manage a particular quality audit.
Baseline Audit:	A full TQSA done for a new or potential TQSA participant.
Commodity Credit Corporation (CCC):	Government-owned corporation which provides financing for farm programs, and for the purchase, storage and disposal of commodities in federal stocks. FSA employees are the administrative agents for the CCC.
Corrective Action Request (CAR):	Report showing major nonconformities found during an audit. Auditee is required to respond to the report by identifying root causes, short and long-term corrective actions, and measures to prevent recurrence of the problem. Refer to Form KC-03TQ (Section 5).
Destination Review:	Reviews conducted at a point in the commodity distribution chain for the purpose of verifying product conformance to the applicable standards or specifications.
Documentation:	The systematic, orderly, and understandable descriptions and records of those policies and procedures affecting product and service quality.
Frequency Level (FL):	Indicates a supplier's level of proficiency in the TQSA, and designates the number of full audits during a 12 month cycle.
Good Manufacturing Practices (GMPs):	Practices dictated by Food and Drug Administration as those to be used in common industry practice. Refer to the Code of Federal Register (CFR) Title 21 Part 110, as amended.

Inspection:	The activities, such as measuring, examining, testing, and gauging one or more characteristics of a product or service, and comparing these with specified requirements to determine quality.
ISO:	The International Organization for Standardization.
ISO 9001:2000	The body of standards pertaining to quality management; published by ISO.
KCCO:	The Kansas City Commodity Office.
Nonconformance:	Deviation from applicable standards, requirements, or contract terms.
Nonconformity:	The non-fulfillment of specified requirements. Major nonconformities are those observations which occur in significant frequency, are severe in nature, or result in quality system breakdown. Minor nonconformities are merely observations or concerns, and do not usually indicate a system breakdown.
Objective evidence:	Verifiable qualitative or quantitative information, records, or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element, which is based on observation, measurement, or test and which can be verified.
Observation:	A statement of fact made during an audit and substantiated by objective evidence.
Operation:	The production of a product that is the same as, or similar to, the product being sold to USDA/CCC.
Procedures:	The documented practice(s) defining the who, what, and when of quality or production activities. Procedures are typically used at the departmental level, and may involve more than one department.
Procurement:	The acquisition of goods or services for use by the customer.
Quality:	The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs of the customer.

Quality Audit:	(See audit).
Quality Assurance:	All the planned and systematic activities implemented within a quality system that provide confidence that requirements for quality are being fulfilled.
Quality Control:	The operational techniques and activities used to fulfill the requirements of quality.
Quality Management:	The aspect of overall management function that determines and implements the quality policy.
Quality Manual:	The document stating the quality policy and describing the quality system of the organization. It should state the company's total commitment to quality.
Quality Plan:	A document setting out the specific quality practice, resources, and activities relevant to a particular product, process, service, contract, or project.
Quality Policy:	The overall intention and direction of an organization in regards to quality as formally expressed by top management.
Quality system:	The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.
Random Sampling:	Sampling of finished product according to a statistical plan in order to attain a representative sample of a larger unit.
Record:	Document which furnishes objective evidence of activities performed or past results achieved.
Rework:	Action taken on a nonconforming product so that it will fulfill the specified requirements.
Specification:	The document that prescribes the requirements that the product or service has to meet.
Summary:	Form reporting audit dates, score, and total auditor hours. Refer to Form KC-01TQ in Section 4 of these guidelines.

Supplier:	Any primary manufacturer or regular dealer who is doing business with USDA/CCC.
Surveillance audits:	Audits of the supplier's facility which may be unannounced and is intended to review only a portion of the supplier's quality system, confirm successful completion of corrective action requests, or to gather information requested by KCCO. May also include random sampling of finished product for analytical testing.
Testing:	A means of determining the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating actions and conditions.
Traceability:	The ability to trace the history, application, or location of an item or activity and like items or activities by means of recorded information.
Total Quality Management:	Management approach of an organization, centered on quality, based on the participation of all its members and aiming at long-term success through customer satisfaction, and benefits to all members of the organization and to society.
TQSA (Total Quality Systems Audit):	(See audit.) TQSA is the method of supplier verification utilized by FSA to approve suppliers for some USDA/CCC food assistance programs.
TQSA Report:	Report generated upon completion of an audit which shows all observations, findings, and major and minor nonconformities found by the auditor(s). Refer to Form TQ-003 (Section 4).

Section 4

TQSA Summary, Form KC-01TQ
TQSA Report, Form TQ-003

Insert current revision of
Form KC-01TQ, TQSA Summary
Form TQ-003, TQSA Report.

KC-1TQ

U.S. DEPARTMENT OF AGRICULTURE
Farm Services Agency

TOTAL QUALITY SYSTEMS AUDIT - AUDIT SUMMARY

SECTION A - BUSINESS INFORMATION

1. TYPE OF AUDIT

2. CONTROL NO.	3. VENDOR/PLANT CODE	4. SMALL BUSINESS? ☐ YES ☐ NO

5. COMPANY NAME

6. PRODUCTS

7a. LOCATION OF MAIN OFFICE (Complete mailing address, including ZIP		8a. LOCATION OF PLANT (Complete mailing address, including ZIP	
7b. PHONE NO. (include area	7c. FAX NO.	8b. PHONE NO. (include area	8c. FAX
9a. CONTACT PERSON 9b. TITLE		10. HOURS OF OPERATION	

SECTION B - AUDIT INFORMATION

11. DATE(s)	12. CARs ISSUED	13. DATE CARs DUE	14. TOTAL	15. FREQUENCY LEVEL

16. COMMENTS

17. AUDITORS	18. HOURS
SECTION C - CERTIFICATION 19. TOTAL HOURS	

I hereby certify that I agree with the results of the audit and the total hours billed.

20. COMPANY REPRESENTATIVE SIGNATURE	21. DATE

TQSA Report, Form TQ-003

Total Quality Systems Audit

March 23, 2004

AUDIT Checklist Draft Rev 2/4/04

Lead Auditor		**Date Completed**
Plant Location		**Date Next Audit**
Auditor		
Plant Location		
Contact Person	**Title**	**Fax No.**
Phone Number	**Products**	**Multi Produc**
Vendor/Plant Co	**Total Audit I**	**Parent Entit**
Location Main O	**Type of Aud**	**Main Office P**

SECTION 4.1 General Requirements Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Has the organization's quality management system been established, documented, implemented, maintained and continually improved its effectiveness? (ISO 4.1)						
2.	Has the organization: a. identified the processes needed for the quality management system and their application throughout? b. determined the sequence and interaction of these processes? c. determined criteria and methods needed to ensure the effective operation and control of these processes? d. ensured the availability of resources and information necessary to support the operation and monitoring of these processes? e. measured, monitored, and analyzed these processes? f. implemented actions necessary to achieve planned results and continual improvement of these processes? (ISO 4.1)						
3.	Has the organization identified outsourced processes within its quality management system? (ISO 4.1)						
4.	Does the organization ensure control over outsourced processes that affect product conformity with requirements? (ISO 4.1)						

TQSA Report, Form TQ-003

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SECTION 4.1 General Requirements Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
5.	Has the organization managed internal and external (outsourced) processes in accordance with a Quality Management System? (ISO 4.1)						

TQSA Report, Form TQ-003

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SECTION 4.2 Documentation Requirements Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Does the organization's quality management system documentation include: a. a documented statement of a quality policy and quality objectives? b. a quality manual? c. documented procedures in the following areas? Control of documents Control of records Internal audit Control of nonconforming product Corrective action Preventive action Food Safety Program Good Manufacturing Practices Good Lab Practices d. documents required to ensure the effective planning, operation and control of its processes (internal documents)? (ISO 4.2.1)						
2.	Has the organization established and maintained a quality manual that includes: a. the scope of the quality management system? b. the documented procedures established for the quality management system or reference to them? c. a description of the interaction between the processes of the quality management system? (ISO 4.2.2)						
3.	Does the organization control documents required by the quality management system? (ISO 4.2.3)						

SECTION 4.2 Documentation Requirements Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
4.	Has the organization established a documented procedure to define the controls needed to: a. approve documents for adequacy prior to issue? b. review and update as necessary and reapprove documents? c. ensure that changes and the current revision status of documents are identified? d. ensure that relevant versions of applicable documents are available at points of use? e. ensure that documents remain legible and readily identifiable? f. ensure that documents of external origin are identified and their distribution controlled? g. prevent the unintended use of obsolete documents? h. apply suitable identification to obsolete documents if they are retained for any purpose? (ISO 4.2.3)						
5.	Has the organization established and maintained records to provide evidence of: a. production or service conformity to requirements? b. effective operation of the quality management system? (ISO 4.2.4)						
6.	Are records legible, readily identifiable and readily retrievable? (ISO 4.2.4)						

TQSA Report, Form TQ-003

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SECTION 4.2 Documentation Requirements Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
7.	Has the organization established a documented procedure to define controls needed for records: identification? storage? protection? retrieval? retention time? (3 years per USDA-1 for contracts) disposition or disposal? (ISO 4.2.4)						

TQSA Report, Form TQ-003

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SECTION 5.1 Management Commitment Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Has top management provided evidence of organization's commitment to the development and implementation of the quality management system and continually improving its effectiveness by: a. communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements? b. establishing the quality policy? c. ensuring that quality objectives are established? d. conducting management reviews? e. ensuring the availability of resources? (ISO 5.1)						

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SECTION 5.2 Customer Focus Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Has top management ensured that customer requirements are determined, met and aimed at enhancing customer satisfaction? (see 7.2.1 and 8.2.1) (ISO 5.2)						

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SECTION 5.3 Quality Policy Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Has top management ensured that the quality policy: a. is appropriate to the purpose of the organization? b. includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system? c. provides a framework for establishing and reviewing quality objectives? d. is communicated and understood within the organization? e. is reviewed for continuing suitability? (ISO 5.3)						

TQSA Report, Form TQ-003

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SECTION 5.4 Planning Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Has top management ensured that quality objectives, including those needed to meet requirements for products (see7.1), have been established at relevant functions and levels within the organization? (ISO 5.4.1)						
2.	Are the quality objectives measurable and consistent with quality policy? (ISO 5.4.1)						
3.	Has top management ensured that: a. the planning of the quality management system is carried out in order to meet the outlined requirements as well as the quality objectives? b. the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented? (ISO 5.4.2)						

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SECTION 5.5 Responsibility, Authority and Communication Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Has top management ensured that the responsibilities and authorities are defined and communicated within the organization? (ISO 5.5.1)						
2.	Has top management appointed a member of management as the Management Representative? (ISO 5.5.2)						
3.	Does the management representative, irrespective of other responsibilities, have responsibility and authority that includes: a. ensuring that processes needed for the quality management system are established, implemented and maintained? b. reporting to top management on the performance of the quality management system and any need for improvement? c. ensuring the promotion of awareness of customer requirement throughout the organization? (ISO 5.5.2)						
4.	Has top management ensured that: a. appropriate communication processes are established within the organization? b .communication takes place regarding the quality management system? (ISO 5.5.3)						

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SECTION 5.6 Management Review Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Does the organization's top management review the quality management system at planned intervals, to ensure its continuing a. suitability? b. adequacy? c. effectiveness? (ISO 5.6.1)						
2.	Does the organization's management review include assessing opportunities for improvement? (ISO 5.6.1)						
3.	Does the organization's management review include assessing the need for changes to the quality management system, including the quality policy and objectives? (ISO 5.6.1)						
4.	Does the organization maintain records from the organization's management reviews? (ISO 5.6.1)						
5.	Do inputs to the management review include information on: a. result of audits? b. customer feedback? c. process performance and product conformity? d. status of preventive and corrective actions? e. follow-up actions from previous management reviews? f. changes that could affect the quality management system? g. recommendations for improvement? h. control of suppliers? i. food safety programs? (ISO 5.6.2)						

SECTION 5.6 Management Review Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
6.	Do outputs from the management review include any decisions and actions related to: a. improvement of the effectiveness of the quality management system and its processes? b. improvement of product related to customer requirements? c. resource needs? (ISO 5.6.3)						

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SECTION 6.1 Provision of Resources Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Has the organization determined and provided the resources needed: a. to implement and maintain the quality management system and continually improve its effectiveness? b. to enhance customer satisfaction by meeting customer requirements? (ISO 6.1)						

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SECTION 6.2 Human Resources Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Are personnel who perform work affecting product quality competent on the basis of appropriate: a. education? b. training? c. skills? d. experience? (ISO 6.2.1)						
2.	Has the organization: a. determined the necessary competence for personnel performing work affecting product quality? b. provided training or taken other actions to satisfy needs? c. evaluated the effectiveness of the actions taken? d. ensured that the personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives? e. maintained appropriate records of education, training, skills and experience? (see 4.2.4) (ISO 6.2.2)						

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SECTION 6.3 Infrastructure Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Has the organization determined, provided, and maintained the infrastructure needed to achieve conformity to product requirements? (ISO 6.3)						
2.	Does infrastructure include, as applicable: a. buildings, work space and associated utilities? b. process equipment (both hardware and software)? c. supporting services (such as transport or communication)? (ISO 6.3)						

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SECTION 6.4 Work Environment Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Does the organization identify and manage the work environment needed to achieve conformity to product requirement? (ISO 6.4)						
2.	Has the organization conducted security vulnerability assessment and established procedures that address: a. access for authorized personnel only? b. general security of the physical structures and grounds? c. emergency action planning? d. contact information for local authorities? e. contractors and visitors prior to gaining access to facility?						
3.	Does the organization identify hazards and/or critical situations and is there a plan to control these situations? (HACCP, Food Safety Program)						
4.	Are there policies and procedures in place to control the work environment and operating conditions that contribute to production of safe and wholesome products and are they followed? a) Good Manufacturing Practices (GMPs) b) Sanitation Programs c) Pest Control Programs						

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SECTION 7.1 Planning of Product Realization Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Does the organization plan and develop the processes needed for product realization? (ISO 7.1)						
2.	Is the planning of product realization consistent with the requirements of the other processes of the quality management system? (see 4.1) (ISO 7.1)						
3.	In planning product realization, has the organization determined the following, as appropriate: a. quality objectives and requirements for the product? b. the need to establish processes, documents, and provide resources specific to the product? c. required verification, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance? d. records needed to provide evidence that the realization processes and resulting product meet requirements? (see 4.2.4) (ISO 7.1)						
4.	Is the output of this planning in a form suitable for the organization's method of operation? (ISO 7.1)						

SECTION 7.2 Customer-Related Product Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Has the organization determined: a. requirements specified by the customer, including the requirements for delivery and post-delivery activities? b. requirements of food security, rail and truck inspections, seals on containers,cars and trailers? c. requirements not stated by the customer but necessary for specified or intended use, where known? d. statutory, regulatory and contractual requirements related to the product? e. applicable domestic origin compliances verified? f. any additional requirements determined by the organization? (ISO 7.2.1)						
2.	Does the organization review the requirements related to the product? (ISO 7.2.2)						
3.	Is the review conducted prior to the organization's commitment to supply a product to the customer (for example, submission of tenders, acceptance of contracts, orders)? (ISO 7.2.2)						
4.	Does the review ensure that: a. product requirements are defined? b. contract or order requirements differing from those previously expressed are resolved? c. the organization has the ability to meet the defined requirements? (ISO 7.2.2)						
5.	Are records of the results of the review and actions arising from the review maintained? (see 4.2.4)? (ISO 7.2.2)						

SECTION 7.2 Customer-Related Product Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
6.	Where the customer provides no documented statement of requirement, does the organization confirm the customer requirements before acceptance? (ISO 7.2.2)						
7.	Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements? (ISO 7.2.2)						
8.	Does the organization determine and implement effective arrangements for communicating with customers in relation to: a. product information? b. enquiries, contracts, or order handling, including amendments? c. customer feedback, including customer complaints? (ISO 7.2.3)						

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SECTION 7.4 Purchasing Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Does the organization ensure that purchased product conforms to specified purchase requirements? (ISO 7.4.1)						
2.	Is the type and extent of control applied to the supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product? (ISO 7.4.1)						
3.	Does the organization evaluate and select suppliers based on their ability to supply product in accordance with organization's requirements? (ISO 7.4.1)						
4.	Are the criteria for selection, evaluation, and reevaluation established? (ISO 7.4.1)						
5.	Are records of the results of evaluations and any necessary actions arising from the evaluation maintained? (see4.2.4) (ISO 7.4.1)						
6.	Does the organization's purchasing information describe the product to be purchased, including, where appropriate: a. requirements for approval of product, procedures, processes and equipment? b. requirements for qualification of personnel? c. quality management system requirements? (ISO 7.4.2)						
7.	Does the organization ensure the adequacy of specified purchase requirements prior to their communication to the supplier? (ISO 7.4.2)						

SECTION 7.4 Purchasing Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
8.	Has the organization identified and implemented the inspection or other activities necessary for ensuring that purchased (received) products meet specified purchase requirements and food security issues? (ISO 7.4.3)						
9.	Where the organization or its customers intend to perform verification at the supplier's premises, has the organization stated the intended verification arrangements and method of product release in the purchasing information? (ISO 7.4.3)						

SECTION 7.5 Production and Service Provision Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Does the organization plan and carry out production and service provision under controlled conditions? (ISO 7.5.1)						
2.	Do these controlled conditions include, as applicable: a. availability of information that describes the characteristics of the product? b. availability of work instruction, as necessary? c. use of suitable equipment? d. availability and use of monitoring and measurement? e. implementation of monitoring and measurement? f. implementation of release, delivery and post-delivery activities? (ISO 7.5.1)						
3.	Where appropriate, does the organization identify the product by suitable means throughout production realization? (ISO 7.5.3)						
4.	Does the organization identify the product status with respect to monitoring and measurements requirements? (ISO 7.5.3)						
5.	Where traceability is a requirement, does the organization control and record the unique identification of the product? (see 4.2.4) (ISO 7.5.3)						
6.	Does the organization have provisions to conduct routine internal mock recalls for: a. raw material forward? b. lot code backward? c. lot code forward?						
7.	Are the results of these internal mock recalls documented and self-assessments performed at least annually?						
8.	Does the organization maintain a recall/crisis response management system?						

SECTION 7.5 Production and Service Provision Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
9.	Are documents of recall and crisis management activities on file?						
10.	Does the organization exercise care with customer property while it is under organization's control or while using it? (ISO 7.5.4)						
11.	Does the organization identify, verify, protect and safeguard customer property provided for use or incorporation into the product? (ISO 7.5.4)						
12.	Is any customer property that is lost, damaged, or otherwise found to be unsuitable for use reported to the customer? (ISO 7.5.4)						
13.	Are records maintained for customer property that is lost, damaged, or otherwise found to be unsuitable for use (see4.2.4)? (ISO 7.5.4)						
14.	Does the organization preserve the conformity of product during internal processing and delivery to the intended destination? (ISO 7.5.5)						
15.	Does this preservation include: a. identification? b. handling? c. packaging? d. storage? e. protection? (ISO 7.5.5)						
16.	Is there a security plan in place to insure the product is protected during handling and storage?						
17.	Is this preservation also applied to the constituent parts of a product? (ISO 7.5.5)						

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SECTION 7.6 Control of Monitoring and Measuring Devices Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Does the organization determine: a. the monitoring and measurement to be undertaken? b. the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements? (see7.2.1) (ISO 7.6)						
2.	Does the organization establish processes to ensure that monitoring and measurement can be carried out? (ISO 7.6)						
3.	Are monitoring and measurement carried out in a manner that is consistent with the monitoring and measurement requirements? (ISO 7.6)						
4.	Where necessary to ensure valid results, is measuring equipment: a. calibrated or verified at specific intervals, or prior to use, against measurement standards traceable to international or national measurement standards? Where no such standard exists, is the basis used for calibration or verification recorded? b. adjusted or readjusted as necessary? c. identified to enable the calibration status to be determined? d. safeguarded from adjustments that would invalidate the measurement result? e. protected from damage and deterioration during handling, maintenance and storage? (ISO 7.6)						
5.	Does the organization assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements? (ISO7.6)						

SECTION 7.6 Control of Monitoring and Measuring Devices Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
6.	Does the organization take appropriate action on the equipment and any product affected? (ISO 7.6)						
7.	Does the organization maintain records of the results of calibration and verification? (see 4.2.4) (ISO 7.6)						
8.	When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed? (ISO 7.6)						
9.	Is the confirmation of computer software undertaken prior to initial use and reconfirmed as necessary? (ISO 7.6)						

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SECTION 8.1 General Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Does the organization plan and implement the monitoring, measurement, analysis, and improvement processes needed to: a. demonstrate conformity of the product? b. ensure conformity of the quality management system? c. continually improve the effectiveness of the quality management system? (ISO 8.1)						
2.	Does this include the determination of applicable methods, including statistical techniques and the extent of their use? (ISO 8.1)						

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SECTION 8.2 Measurement and Monitoring Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	As one of the measurements of the performance of the quality management systems, does the organization monitor information relating to customer perception as to whether it has met customer requirements? (ISO 8.2.1)						
2.	Has the organization determined the methods for obtaining and using this information? (ISO 8.2.1)						
3.	Does the organization conduct internal audits at planned intervals to determine whether the quality management system: a. meets the established quality management system requirements? (see 7.1) b. is effectively implemented and maintained? (ISO 8.2.2)						
4.	Has the organization planned the audit program, taking into consideration: a. the status and importance of the processes and areas to be audited? b. the results of previous audits? (ISO 8.2.2)						
5.	Has the organization defined the audit: a. criteria? b. scope? c. frequency? d. methods? (ISO 8.2.2)						
6.	Does the organization ensure objectivity and impartiality of the audit process? (ISO 8.2.2)						
7.	Are auditors disallowed from auditing their own work? (ISO 8.2.2)						
8.	Has the organization documented a procedure defining the responsibilities and requirements for: a. planning and conducting audits? b. reporting results? c. maintaining records? (ISO 8.2.2)						

SECTION 8.2 Measurement and Monitoring Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
9.	Does management, responsible for the area being audited, ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes? (ISO 8.2.2)						
10.	Do follow-up activities include the verification and documentation of the actions taken? (see8.5.2) (ISO 8.2.2)						
11.	Does the organization apply suitable methods for monitoring and measurement of the quality management system processes? (ISO 8.2.3)						
12.	Do these methods demonstrate the ability of the processes to achieve planned results? (ISO 8.2.3)						
13.	When planned results are not achieved, are corrective actions taken to ensure product conformity? (ISO 8.2.3)						
14.	Does the organization monitor and measure the characteristics of the product to verify that product requirements are met? (ISO 8.2.4)						
15.	Is monitoring and measuring of the product characteristics carried out at appropriate stages of the product realization process in accordance with planned arrangements? (see 7.1) (ISO 8.2.4)						
16.	Is the evidence of conformity with the acceptance criteria maintained? (ISO 8.2.4)						
17.	Does organization records indicate the person(s) authorizing release of product? (see 4.2.4) (ISO 8.2.4)						
18.	Does the organization ensure that product release and service delivery does not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by customer? (ISO8.2.4)						

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SECTION 8.3 Control of Nonconforming Product Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Does the organization ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use and delivery? (ISO 8.3)						
2.	Does the organization have a documented procedure which defines controls and related responsibilities and authorities for dealing with nonconforming products? (ISO 8.3)						
3.	Does the organization deal with nonconforming product in one or more of the following ways: a. by taking action to eliminate the detected nonconformity? b. by authorizing its use , release, or acceptance under concession by a relevant authority and, where applicable by customer? c. by taking action to preclude its original intended use or application? (ISO 8.3)						
4.	Are records maintained of the nature of nonconformities and any subsequent actions taken, including concessions obtained? (ISO 8.3)						
5.	When nonconforming product is corrected, does the organization subject it to re-verification to demonstrate conformity to the requirements? (ISO 8.3)						
6.	Does the organization take appropriate action when nonconforming product is detected after delivery or use of the product has started? (ISO 8.3)						

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SECTION 8.4 Analysis of Data Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Does the organization determine, collect, and analyze data to demonstrate the suitability and effectiveness of the quality management system necessary to evaluate where continual improvement of the quality management system can be made? (ISO 8.4)						
2.	Does this include data generated as a result of monitoring and measuring devices and from other relevant sources?						
3.	Does the organization analyze this data to provide information relating to: a. customer satisfaction (see 8.2.1)? b. conformance to product requirements? (see 7.2.1) c. characteristics and trends of processes and products, including opportunities for preventive action? d. suppliers? (ISO 8.4)						

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SECTION 8.5 Improvement Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
1.	Does the organization continually improve the effectiveness of the quality management system through the use of: a. a quality policy? b. quality objectives? c. audit results? d. analysis of data? e. corrective and preventive actions? f. management review? (ISO 8.5.1)						
2.	Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence? (ISO 8.5.2)						
3.	Is corrective action(s) appropriate for the nonconformities encountered? (ISO 8.5.2)						
4.	Does the organization have a documented procedure which defines requirements for: a. reviewing nonconformities (including customer complaints)? b. determining the causes of nonconformities? c. evaluating the need for action to ensure that nonconformities do not reoccur? d. determining and implementing action needed? e. records of results of corrective action taken (see 4.2.4)? f. reviewing corrective action taken? (ISO 8.5.2)						
5.	Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence? (ISO 8.5.3)						

SECTION 8.5 Improvement Checklist Items

Item	Requirement	Pass	Fail	N/A	Type	Value	Observations
6.	Are preventive actions taken appropriate to the effects of the potential problems? (ISO 8.5.3)						
7.	Does the organization have a documented procedure which defines requirements for: a. determining potential nonconformities and their causes? b. evaluating the need for action to prevent occurrence of nonconformities? c. determining and implementing action needed? d. records of results of preventive action taken (see 4.2.4)? e. reviewing preventive action taken? (ISO 8.5.3)						

Section 5

Corrective Action Request, Form KC-03TQ

Insert current revision of Form KC-03TQ, Corrective Action Request

 Form Approval -OMB No. 0560-XXXX

KC-3TQ
(4-9-99)

U.S. DEPARTMENT OF AGRICULTURE
Farm Services

TOTAL QUALITY SYSTEMS AUDIT - CORRECTIVE ACTION REQUEST (CAR)

1. COMPANY NAME		2. CAR
3. PLANT LOCATION		4. AUDIT DATE
5. CONTROL NO.	6. VENDOR/PLANT	7. PRODUCT

OBSERVATIONS MADE BY AUDITOR

8. AREA OF OBSERVATION ITEM

9. OBSERVATION MADE

10. NOTED BY

Signature below constitutes receipt and acknowledgment of the CAR

11. AUDITOR	12. DATE	13. COMPANY REPRESENTATIVE	14. DATE

COMPANY'S CORRECTIVE ACTION

15. Actions to be taken must be reported below. Return this form within 10 working days to the office shown:

USDA-FSA
Kansas City Commodity
Attn: WLED-EB-TQSA
P.O. Box 419205
Kansas City, MO 64141-6205

Phone :
FAX :

16. The following actions have been proposed or completed to correct this occurrence and to prevent recurrence.

17. ASSIGNED TO	18. DEPARTMENT
19. TARGET COMPLETION DATE	20. ACTUAL COMPLETION

Attachment B

Scoring Guidelines

Question Scoring

Within each section, the result for each requirement will be marked in the right hand columns as follows:

Pass = Yes, this requirement has been met and effectively implemented.

Fail = No, this requirement has not been met and/or effectively implemented. Improvement is needed. All failures will then be determined to be major or minor types and recorded. Corrective Action Request(s) – KC-03TQ, CAR(s) will be issued for all major non-conformances.

N/A = Not applicable.

Value

1 = Pass
0 = Fail

*Special Note: A major failure in any requirement of Form TQ-003 would preclude participation in commodity purchase programs until such time corrective action is determined, implemented, and verified as effective.
"Major" will appear under the Type column for all non-compliant observations and findings considered to be system failures with supporting evidence documented under Observations column. All major failures will result in CAR(s) being issued.
"Minor" will appear under the Type column for all non-compliant observations considered to require improvement with supporting evidence documented under Observations column. CAR(s) will not be issued for minor failures.

Final Scoring

The final score is calculated by taking the percentage of the sum of requirement values divided by the total number of applicable requirements answered. (Average)

Reporting of Assessment Findings

Observations regarding nonconformities on the auditor checklist should contain detailed information about the findings and evidence. The first page of the TQSA Report, Form TQ-003 should include a summary of the question results and the final score.
All major nonconformities should have a Corrective Action Request (CAR) completed, containing detailed information. CAR(s) should be signed by the auditor(s) and company representative(s) and accompany the assessment report.